

Remarks

Twenty (20) claims remain pending in the application: Claims 9-10, 12-16, and 21-33, of which Claims 9, 28, and 29 are independent. Claims 9, 12, 14, 16, 22-24, 28, 29, and 32 are currently amended. Applicants respectfully request reconsideration of the pending claims, in view of the comments below.

Amendments to the Specification

The specification is amended to correct small errors. In paragraph [0019], the word “other” is deleted because a BTE unit is not a “head-mounted external component”, as used throughout the specification, since BTE units are mounted “behind the ear”, not to the head. On the other hand, paragraphs [0029] and [0030] are amended to clarify that headpieces *are* external components, as can be found throughout the specification as filed. It is submitted that no new matter is added.

Amendments to the Claims

As shown in references identified on the Information Disclosure Statement (IDS) submitted herewith, cochlear implant systems usually include a headpiece, which is usually connected by a cord to a speech processor. The headpiece is attached to the surface of the head behind the ear, and sends signals from the speech processor through the skin to the implanted receiver. Although the headpiece may^{1,2,3} or may not include a microphone, and may be attached by magnetic^{4,5,6,7,8} or nonmagnetic⁹ means, and may be attached to a BTE

¹ Cochlear implants bring identity change, Otolaryngology – Head and Neck Surgery, Breakthrough, Autumn 2004, p. 6.

² What Are Cochlear Implants and How Does it Work? - Cochlear Implants - My Baby's Hearing. Retrieved January 20, 2009 from <http://www.babyhearing.org/HearingAmplification/Cochlear/whathow.asp>

³ Cochlear Implants and Children, ADVANCE FOR AUDIOLOGISTS SEPTEMBER/OCTOBER 2000, p. 26. www.advanceforAUD.com

⁴ What Are Cochlear Implants and How Does it Work? - Cochlear Implants - My Baby's Hearing. Retrieved January 20, 2009 from <http://www.babyhearing.org/HearingAmplification/Cochlear/whathow.asp>

⁵ Cochlear Implants and Children, ADVANCE FOR AUDIOLOGISTS SEPTEMBER/OCTOBER 2000, p. 26. www.advanceforAUD.com

⁶ BionicEar.com - Harmony Cochlear Implant by Advanced Bionics

⁷ COCHLEAR IMPLANT PROGRAMME, Cochlear Implants, Speech Laboratory, Audiology, E.... Retrieved January 20, 2009 from http://www.kkrenthospital.org/surgery_cochlear.htm

⁸ Welcome to Spokane Ear, Nose&Throat Clinic, P.S. Surgery Center. Retrieved January 20, 2009 from http://www.spokaneent.com/cochlear_implants.html

⁹ See U.S. Patent No. 6,560,488 to Crawford and 6,275,736 to Kuzma, et al.

processor,^{10,11,12} or body worn processor^{13,14} wirelessly or by a cord,^{15,16,17,18} or not at all,¹⁹ the term “headpiece,” as used in the art and in the present application, refers to that part of the system that attaches to the head^{20,21,22,23,24} and communicates with the implanted device.^{25,26,27,28} usually transcutaneously via an inductive,²⁹ RF,^{30,31,32} or optical link. However, to expedite prosecution, and to avoid the possibility that “headpiece” might be construed as being limited to head-mounted external components *only for cochlear implants*, the claims have been amended to replace the word “headpiece” with “head-mounted external component...configured to communicate with an implanted device” to clarify that such components for implantable hearing

¹⁰ Cochlear Implants and Children, ADVANCE FOR AUDIOLOGISTS SEPTEMBER/OCTOBER 2000, p. 26. www.advanceforAUD.com

¹¹ Welcome to Spokane Ear, Nose&Throat Clinic, P.S. Surgery Center. Retrieved January 20, 2009 from http://www.spokaneent.com/cochlear_implants.html

¹² Cochlear Implant . Medical Articles of Interest from Garamchai.Com. Retrieved January 20, 2009 from <http://www.garamchai.com/DesiTrendsMedical1.htm>

¹³ What Are Cochlear Implants and How Does it Work? - Cochlear Implants - My Baby's Hearing. Retrieved January 20, 2009 from <http://www.babyhearing.org/HearingAmplification/Cochlear/whathow.asp>

¹⁴ Cochlear Implants and Children, ADVANCE FOR AUDIOLOGISTS SEPTEMBER/OCTOBER 2000, p. 26. www.advanceforAUD.com

¹⁵ What Are Cochlear Implants and How Does it Work? - Cochlear Implants - My Baby's Hearing. Retrieved January 20, 2009 from <http://www.babyhearing.org/HearingAmplification/Cochlear/whathow.asp>

¹⁶ Cochlear Implants and Children, ADVANCE FOR AUDIOLOGISTS SEPTEMBER/OCTOBER 2000, p. 26. www.advanceforAUD.com

¹⁷ Cochlear Implant . Medical Articles of Interest from Garamchai.Com. Retrieved January 20, 2009 from <http://www.garamchai.com/DesiTrendsMedical1.htm>

¹⁸ Welcome to Spokane Ear, Nose&Throat Clinic, P.S. Surgery Center. Retrieved January 20, 2009 from http://www.spokaneent.com/cochlear_implants.html

¹⁹ See Fig. 5 of the present invention

²⁰ Cochlear implants bring identity change, Otolaryngology – Head and Neck Surgery, Breakthrough, Autumn 2004, p. 6.

²¹ What Are Cochlear Implants and How Does it Work? - Cochlear Implants - My Baby's Hearing. Retrieved January 20, 2009 from <http://www.babyhearing.org/HearingAmplification/Cochlear/whathow.asp>

²² UCSF - Cochlear Implant. Retrieved January 20, 2009 from <http://cochlearimplant.ucsf.edu/page.asp?bodyid=implantsystem>

²³ COCHLEAR IMPLANT PROGRAMME, Cochlear Implants, Speech Laboratory, Audiology, E.... Retrieved January 20, 2009 from http://www.kkrenthospital.org/surgery_cochlear.htm

²⁴ See U.S. Patent No. 6,560,488 to Crawford and 6,275,736 to Kuzma, et al.

²⁵ What Are Cochlear Implants and How Does it Work? - Cochlear Implants - My Baby's Hearing. Retrieved January 20, 2009 from <http://www.babyhearing.org/HearingAmplification/Cochlear/whathow.asp>

²⁶ Welcome to Spokane Ear, Nose&Throat Clinic, P.S. Surgery Center. Retrieved January 20, 2009 from http://www.spokaneent.com/cochlear_implants.html

²⁷ U.S. Patent No. 6,275,736 to Kuzma, et al. Fig. 2

²⁸ U.S. Patent No. 6,560,488 to Crawford

²⁹ U.S. Patent No. 7,349,741 to Maltan, et al., Fig. 1 and 3, and col. 4, lines 10-13.

³⁰ What Are Cochlear Implants and How Does it Work? - Cochlear Implants - My Baby's Hearing. Retrieved January 20, 2009 from <http://www.babyhearing.org/HearingAmplification/Cochlear/whathow.asp>

³¹ Cochlear Implants and Children, ADVANCE FOR AUDIOLOGISTS SEPTEMBER/OCTOBER 2000, p. 26. www.advanceforAUD.com

devices other than cochlear implants are also included. Support for this change is found in the specification in paragraph [0019], which says, “The present invention adds functionality to cochlear implant and/or implantable hearing aid devices and systems without adding substantial weight or size to these associated devices or systems to their associated, head-mounted, external components.” The following arguments to the Office Action rejections will use the term “headpiece”, since that is how the claims stood at the time the Office Action was written; however, the arguments apply equally to the language as amended.

Claim Rejections

Claim Rejections - 35 USC § 102

Money (U.S. patent 6,496,734)

The Office Action rejected Claims 9-10, 12-14, 16, 21, 23 and 28-33 under 35 U.S.C. §102(a) as being anticipated by Money (U.S. patent 6,496,734). The Office Action stated:

“Money teaches a method and apparatus of a behind-the ear unit (16), a headpiece (17), and an assistive listening device cap (15, 21) configured to attach to the headpiece (17) and to be worn external to a patient’s body (figure 1).

“The assistive listening cap (15, 21) includes data communication electronics and is configured to mechanically attach to the exterior surface of the headpiece (17, figure 1), and the data communication electronics are configured to communicate with corresponding communication electronics within the headpiece (17).”

The words of a claim must be given their “plain meaning” unless such meaning is inconsistent with the specification. *MPEP 2111.01§I* “Plain meaning” refers to the ordinary and customary meaning given to the term by those of ordinary skill in the art. *MPEP 2111.01§III* See *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997), in which the court held that the “PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant’s specification.” The ordinary and customary meaning of a term may be evidenced by a variety of sources, including “the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms,

³² Cochlear Implant . Medical Articles of Interest from Garamchai.Com. Retrieved January 20, 2009 from

and the state of the art.” *Phillips v. AWH Corp.*, 415 F.3d at 1314, 75 USPQ2d at 1327. If extrinsic reference sources, such as dictionaries, evidence more than one definition for the term, the intrinsic record must be consulted to identify which of the different possible definitions is most consistent with applicant’s use of the terms. *Brookhill-Wilk 1*, 334 F. 3d at 1300, 67 USPQ2d at 1137; see also *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998).

Here, it is respectfully submitted that Money discloses an RF coil (21), which impliedly is housed within a headpiece as is known in the art³³. In contrast, the element identified in the Office Action as the “headpiece” is actually an implanted receiver stimulator unit (17), which is implanted beneath the scalp and thus does not attach to the head and does not transmit a signal to the implanted device (because it *is* the implanted device). Therefore, the implanted receiver stimulator unit (17) cannot properly be referred to as a “headpiece”.

Furthermore, all independent Claims 9, 28, and 29 require a *cap* configured to attach to a head-mounted external component configured to communicate with an implanted device and worn external to a patient’s body. As evidenced by Figs. 1, 2, 5, and 6 of the present application and the description in paragraphs [0008], [0019], and [0029] of the cap as being “placed on top” of a headpiece, the word “cap” is used in the present application in the sense of a “cover”^{34, 35, 36}. Money does not teach a cap of any kind, nor one configured to attach to the implied headpiece containing RF coil (21) (and nor to the implanted receiver stimulator unit (17), which is implanted in the body). Furthermore, Money does not teach a cap configured to *mechanically attach to the exterior surface* of the headpiece as required in claim 9, and the features asserted to be the cap in the Office Action (speech processor 15 and RF coil 21) do not attach to the exterior surface of the component asserted to be the headpiece (implanted

<http://www.garamchai.com/DesiTrendsMedical1.htm>

³³ What Are Cochlear Implants and How Does it Work? - Cochlear Implants - My Baby's Hearing. Retrieved January 20, 2009 from <http://www.babyhearing.org/HearingAmplification/Cochlear/whathow.asp>

³⁴ cap. (n.d.). *Webster's New Millennium™ Dictionary of English, Preview Edition (v 0.9.7)*. Retrieved January 21, 2009, from Dictionary.com website: <http://dictionary.reference.com/browse/cap>: Anything resembling or suggestive of a covering for the head in shape, use, or position: *a cap on a bottle*.

³⁵ cap. Retrieved January 21, 2009, from <http://www.yourdictionary.com/cap> : Definition: A caplike part or thing; cover or top, as the cap-shaped part of a mushroom, a small metal cover for a bottle, the cover over a camera lens or other projecting or end part, a kneecap, an artificial crown for a tooth, a mountain top, or the capital of a column. Synonyms: A cover. top, lid, stopper

³⁶ cap. (2009). In *Merriam-Webster Online Dictionary*. Retrieved January 21, 2009, from <http://www.merriam-webster.com/dictionary/cap>: Something that serves as a cover or protection especially for a tip, knob, or end: a bottle cap. An overlaying or covering structure.

receiver stimulator unit 17) because they are on opposite sides of the scalp. Therefore, the Money reference does not meet the claim limitations of the present invention, because it does not teach a cap configured to attach to a head-mounted external component configured to communicate with an implanted device and worn external to a patient's body, as required in all independent Claims 9, 28, and 29. It is respectfully requested that this rejection be withdrawn.

Furthermore, Claim 10 requires that the behind-the-ear unit includes a speech processor. It is submitted that the only element described or illustrated in Money as being mounted behind the ear is microphone 16, which provides sound signals to the speech processor 15 (col. 4, lines 61-64 and Fig. 1); microphone 16 does not itself *include* a speech processor.³⁷ It is respectfully submitted that, for that additional reason, Money does not teach the invention of Claim 10. Therefore, it is respectfully requested that this rejection be withdrawn.

Maltan (U.S. patent 7,349,741)

The Office Action rejected Claims 9, 10, 12-15, 28, and 29-33 under 35 U.S.C. §102(e) as being anticipated by Maltan (U.S. patent 7,349,741). The Office Action stated:

"...Maltan et al. teaches a method and apparatus of a behind-the-ear unit (36, 36a, 36b, 36c, 36d), an implantable hearing device (12, 14), a headpiece (50, figures 3, 4), and an assistive listening device cap (20, figure 4) configured to attach to the headpiece (50) and to be worn external to a patient's body.

"The assistive listening cap (20) includes data communication electronics and is configured to mechanically attach to the exterior surface of the headpiece (50), and the data communication electronics are configured to communicate with corresponding communication electronics within the headpiece (50)."

Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999). In addition to references cited in the IDS submitted herewith describing a headpiece as used in the art, paragraph [0008] of the present invention states, "Cochlear implant headpieces attach to the head, not the ear." It is respectfully submitted that Maltan et al. properly identifies element 20

³⁷ Col. 5, lines 41-44 cited in the Office Action discusses division between processing functions of the receiver / stimulator unit 17 and the speech processor 15, and gives an example of a fully implantable device, none of which appears to support the Office Action assertion that "Money teaches the behind-the-ear unit including a cochlear implant speech processor".

as a headpiece containing coil 22 for coupling, either inductively or through an RF link, to another coil in the implantable cochlear stimulator (ICS) 12 (col. 4, lines 10-12). On the other hand, element 50 shown in FIG. 4 is a sound processor 50 configured to be attached to the *ear*, and is therefore *not* a headpiece as explained supra. Furthermore, there is no teaching of sound processor 50 having a transmitting coil that sends a signal through the skin to the implanted cochlear implant. The charging/communication coil 56 within sound processor 50 provides a means through which a charging signal may be received from an external source for recharging the power source 60 or to change the operating parameters using a programming device 80 or remote control 70, but there is no teaching of coil 56 within sound processor 50 used for transmitting a signal through the skin to the ICS. Therefore, sound processor 50 is not a headpiece.³⁸ Therefore, the Maltan reference does not meet the claim limitations of the present invention, since it does not have a cap configured to attach to a head-mounted external component configured to communicate with an implanted device and worn external to a patient's body, as required in all independent claims 9, 28, and 29. It is respectfully requested that this rejection be withdrawn.

Claim Rejections - 35 USC § 103

Money (U.S. patent 6,496,734)

Claims 15, 22, 24-27, and 33 were rejected under 35 U.S.C. §103(a) as being unpatentable over Money (U.S. patent 6,496,734). The Office Action stated:

“Regarding claims 15, 22, 24-27 and 33, as interpreted in a different manner, Money does not specifically teach a power source as claimed in claims 15 and 33. However, providing power source for an implanted hearing device is known in the art.

“Therefore, it would have been obvious to one skilled in the art to provide a power source in the speech processor (15) of the implanted hearing device of Money for better providing a power source to the data communication electronics.

“Regarding claims 22 and 24, Money teaches the data communication electronics of the listening device cap (21) that are configured to communicate with the communication electronics of the headpiece (17) through wireless signals as claimed (col. 4, lines 59-61). Money does not specifically teach the direct electrical contacts or electrically conductive wire as claimed.

³⁸ Furthermore, element 36 is an ear hook and is designed to fit *over* the ear, and is not properly referred to in the art as a *behind-the-ear* unit, although it may be used *with* behind-the-ear sound processor 50 shown in Fig. 4, such as shown in embodiment 36a to position a microphone 54' at the end of a boom 37.

"However, it would have been obvious to one skilled in the art to provide the wireless or wired signals such as the direct electrical contacts or electrically conductive wire for the desired purpose of better transmitting signals between the data communications electronics of the listening device cap (21) and the communication electronics of the headpiece (17) depending on the applications.

"Regarding claims 25-26, Money does not specifically teach a primary battery or a rechargeable battery within the listening device cap (15, 21). However, providing a power source for an implanted hearing device is known in the art.

"Therefore, it would have been obvious to one skilled in the art to provide any power source in the assistive listening device cap (15, 21) such as a primary battery or a rechargeable battery for better providing a power source to the data communication electronics."

As explained above, Money does not teach a cap of the present invention. Therefore, Office Action assertions that it would have been obvious to add certain power sources or wired or wireless connections to Money to produce applicant's invention is without merit. It is respectfully requested that this rejection be withdrawn.

Maltan (U.S. patent 7,349,741)

Claim 16 was rejected under 35 U.S.C. §103(a) as being unpatentable over Money (U.S. patent 6,496,734) in view of Miller (U.S. patent 6,726,618). The Office Action stated:

"Money does not specifically teach the assistive listening device cap (21) that is configured to mechanically attach to the headpiece (17) by means of magnetic force. However, providing the magnets for positioning and attaching the coil or the RF signal transmitter to the implanted receiver is known in the art."

However, it is respectfully submitted that Money does not teach a cap at all, let alone the assistive listening device cap of the present invention. Furthermore, while it is known to magnetically attach a headpiece to the scalp by providing a magnet in the headpiece for magnetic attraction to a magnet in the implanted cochlear implant, it is submitted that providing a magnet in an assistive listening device cap would not be obvious to one skilled in the art because there is no scalp separating it from the headpiece, and therefore there would have been no motivation to look to magnets for attachment because any of the usual mechanical attachment means would be possible for attaching the cap to the headpiece, such as Velcro, adhesive, glue, pocketed, threaded, or snap-on.

The Office Action goes on to state:

"Miller teaches the external transmitter comprising a coil element (204) that is attached to the implanted receiver (118) by the magnets (102, 206).

"Therefore, it would have been obvious to one skilled in the art to provide the magnets, as taught by Miller, to the assistive listening device cap (21) and the headpiece (17) of the Money device for better positioning the cap and the headpiece to the wearer."

However, it is respectfully submitted that, while the magnet in the *headpiece* is provided to position the *headpiece* with respect to the implanted cochlear *implant*, the present invention provides a magnet in the *cap* of the present invention to attach the *cap* to the *headpiece*, and, if necessary, places a magnet having increased magnetic strength inside the headpiece for adequate adherence (paragraph [0025]). Therefore, it would not have been obvious to one skilled in the art to provide magnets "*for better positioning the cap and the headpiece to the wearer* (emphasis added)," as asserted in the Office Action. It is respectfully requested that this rejection be withdrawn.

Conclusion

In view of the foregoing, it is respectfully submitted that the claims in the application are in condition for allowance. Reexamination and reconsideration of the application are respectfully requested. Allowance of the claims at an early date is courteously requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is respectfully requested to telephone the undersigned, Liz Bush, at (661) 362-7504 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully Submitted,

February 19, 2009

/Liz Bush/

Mary Elizabeth Bush
Reg. No. 38,402

Address all correspondence to:
Bryant R. Gold, Reg. No. 29,715
Advanced Bionics, LLC
25129 Rye Canyon Loop
Valencia, CA 91355
(661) 362-1771 or (760) 788-8138
Fax: (661) 362-1507

Address all telephone inquiries to:
Liz Bush, Reg. No. 38,402
(661) 362-750